

USSN: 10/699,586  
Group Art Unit: 3739  
Docket No.: 151P11200US01

### REMARKS

Claims 1 – 15 are pending in this application.

Claims 1 – 15 have been rejected. No claims have been allowed.

#### Amendments to the Claims

Claim 1 has been amended to include means for applying electrical current to the stylet to cauterize the dura. Support for this amendment can be found in the specification in paragraph [61] and in claim 2. Claim 2 has been canceled since the subject matter of the claim has been moved to claim 1. No new matter has been added.

#### Rejections Under 35 USC § 102

Claims 1 – 15 have been rejected under 35 USC § 102 as being anticipated by U.S. Patent No. 6,761,718, Madsen et al. These rejections are respectfully traversed.

#### Madsen et al. '718

Madsen et al. '718 discloses a bipolar coagulator which can be passed through the internal lumen of a ventricular catheter previously implanted into a cranial ventricle of a living subject and engaged in-situ. The bipolar coagulator will provide bipolar electrical arc currents for coagulation/cauterization of adherent brain tissues, such as the choroids plexus, which occludes fluid flow into the intake drainage holes in the implanted ventricular catheter.

The bipolar coagulator has a proximal end adapted to be inserted through the lumen of an already inserted ventricular catheter. The bipolar coagulator has two electrodes intended to coagulate adherent brain tissues, such as the choroids plexus, which otherwise would occlude ports in the sidewall of the catheter. Thus, the sole intended purpose of the bipolar coagulator is to clear ports in an already-inserted in-vivo ventricular catheter.

#### Apparatus Claims (1 and 3 – 8)

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Apparatus claims 1 and 3 – 8 all require an “apparatus for making a hole ... in a dura of a patient for the insertion of a catheter.” In contrast, Madsen et al ‘718 discloses a bipolar coagulator for coagulating brain tissue, not for making a hole in the dura, in a catheter already inserted in-vivo, not for the insertion of a catheter. Not only does Madsen et al ‘718 not disclose an apparatus for making a hole in the dura, the apparatus disclosed in Madsen et al ‘718 is not suitable for making a hole in the dura. The electrodes of the bipolar coagulator disclosed in Madsen et al ‘718 are located along the side of the proximal portion of the elongated body in order to match with the ports located on the sides of the catheter. So positioned, the electrodes could not effectively make a hole in the dura. Thus, the bipolar coagulator disclosed in Madsen et al ‘718 fails to anticipate apparatus claims 1 and 3 – 8 for this reason alone.

Further, independent claim 1 also requires the “stylet [have] a second end formed with a tip having a diameter having a predetermined relationship with said first predetermined diameter.” The second end of the elongate body of the bipolar coagulator disclosed in Madsen et al ‘718 has no predetermined relationship with a first predetermined diameter of a hole to be made in the dura. In fact, Madsen et al ‘718 is completely silent on the diameter of the second end of the elongate body. For this additional reason, Madsen et al ‘718 fails to anticipate apparatus claims 1 and 3 – 8.

In addition, claim 1 has been amended to approximately include the additional element of “means for applying an electrical current to said tip of said stylet to cauterize said dura.” The bipolar coagulator disclosed in Madsen et al ‘718 supplies electrical current only to laterally cauterize brain tissue. The bipolar electrodes disclosed in Madsen et al ‘718 operate to cauterize a lateral area between the electrodes provided. In contrast, the unipolar electrode contains a tip electrode which cauterizes the dura contacting the tip of the stylet. Thus, Madsen et al ‘718 fails to anticipate apparatus claims 1 and 3 – 8 for this additional reason alone.

Not only are apparatus claims 1 and 3 – 8 not anticipated, there is no disclosure in Madsen et al ‘718 to teach or suggest (1) use of the apparatus for making a hole in the dura of a patient for the insertion of a catheter, (2) a predetermined relationship between a tip and a hole in

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a dura, or (3) means for applying electrical current to the tip of the stylet. Thus, Madsen et al also fails to render apparatus claims 1 and 3 – 8 unpatentable for obviousness.

Claims 3 – 8 further contain additional limitations on the relationship between the diameter of the tip of the stylet and hole to be made in the dura of the patient. None of these additional limitations are shown or suggested in Madsen et al '718. For these additional reasons, Madsen et al '718 fails to anticipate apparatus claims 3 – 8 and fails to render them obvious.

Thus, apparatus claims 1 and 3 – 8 are believed patentable over Madsen et al '718, the rejections of claims 1 and 3 – 8 are respectfully believed to erroneous, at least over the claims as amended, and should be withdrawn.

#### Method Claims 9 – 15

Method claim 9 requires a method “for making a hole ... in a dura of a patient ... for the insertion of a catheter.” In contrast, Madsen et al '718 discloses a bipolar coagulator for coagulating brain tissue, not for making a hole in the dura, in a catheter already inserted in-vivo, not for the insertion of a catheter. Not only does Madsen et al '718 not disclose an apparatus for making a hole in the dura, the apparatus disclosed in Madsen et al '718 is not suitable for making a hole in the dura. The electrodes of the bipolar coagulator disclosed in Madsen et al '718 are located along the side of the proximal portion of the elongated body in order to match with the ports located on the sides of the catheter. So positioned, the electrodes could not effectively make a hole in the dura. Thus, the bipolar coagulator disclosed in Madsen et al '718 fails to anticipate method claims 9 – 15 for this reason alone.

Method claim 9 also requires “said stylet with a tip having a diameter having a predetermined relationship with said first predetermined diameter” [of a hole in the dura]. The second end of the elongate body of the bipolar coagulator disclosed in Madsen et al '718 has no predetermined relationship with a first predetermined diameter of a hole to be made in the dura. In fact, Madsen et al '718 is completely silent on the diameter of the second end of the elongate body. For this additional reason, Madsen et al '718 fails to anticipate method claims 9 – 15.

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Not only are method claims 9 – 15 not anticipated, there is no disclosure in Madsen et al '718 to teach or suggest (1) use of the apparatus for making a hole in the dura of a patient for the insertion of a catheter, or (2) a predetermined relationship between a tip and a hole in a dura. Thus, Madsen et al also fails to render method claims 9 – 15 unpatentable for obviousness.

Method claims 11 – 15 further require additional limitations on the relationship between the diameter of the tip of the stylet and hole to be made in the dura of the patient. None of these additional limitations are shown or suggested in Madsen et al '718. For these additional reasons, Madsen et al '718 fails to anticipate method claims 11 – 15 and fails to render them obvious.

Thus, method claims 9 – 15 are believed patentable over Madsen et al '718, the rejections of claims 9 – 15 are respectfully believed to erroneous and should be withdrawn.

#### Summary

In view of the amendments made and the arguments presented, claims 1 and 3 – 15 should be allowable, this application should be in condition for allowance and a notice to that is earnestly solicited.

Respectfully submitted,

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